

THERMACHOICETM II UBT System Service Manual

About This Document

Overview

The THERMACHOICE™II UBT System is a software-controlled device designed to ablate uterine tissue by thermal energy. The system is comprised of a single-use balloon catheter, a reusable controller, umbilical cable, and power cord. The THERMACHOICE™II UBT catheter is designed for use only with the THERMACHOICE™II UBT controller.

Purpose

The *THERMACHOICE™II UBT System Service Manual* is to be used as a guide to maintaining and servicing the THERMACHOICE™II UBT System.

Scope

This manual is to be used by all personnel responsible for maintaining and servicing the THERMACHOICE™II UBT System. It provides procedure level detail on maintenance and service. Troubleshooting and repair is to be performed on the system down to the level of field replaceable units (FRU) rather than to the component level.

Audience Description

The primary audience for the manual is trained GyneCare repair personnel, Colorado MEDtech manufacturing personnel, hospital maintenance personnel and biomedical technicians responsible for performing specific maintenance and service operations on-site.

How to Use This Guide

The GyneCare THERMACHOICE™II UBT Service Manual is an important resource when performing maintenance and service. Read the entire document to become familiar with its content and structure. Use Section One to get an overall understanding of the THERMACHOICE™II UBT System. Later sections will provide details for troubleshooting the individual FRUs, removal and replacement of failed FRUs, and additional reference information.

Organization

Section One contains an overview of the system. It includes descriptions of the mechanical and electronic sub-systems.

Section Two covers diagnostics and troubleshooting to help locate the causes of typical system failures, including a table of diagnostic error codes and their meaning and a troubleshooting guide.

Section Three details the field replaceable units including photographs and part numbers.

Section Four covers remediation, including removal and replacement procedures for field replaceable electrical and mechanical assemblies and a procedure for returning the instrument for repair.

Section Five details the maintenance of the system including pressure and temperature calibration, fuse and power cord replacement, cleaning, and disinfection.

Appendix A contains detailed schematics including the functional block diagram, wiring diagram, and discrete components diagram.

Appendix B contains electrical/electronic parts lists and component values.

Appendix C contains a copy of the Operating Manual.

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Section One

System Overview

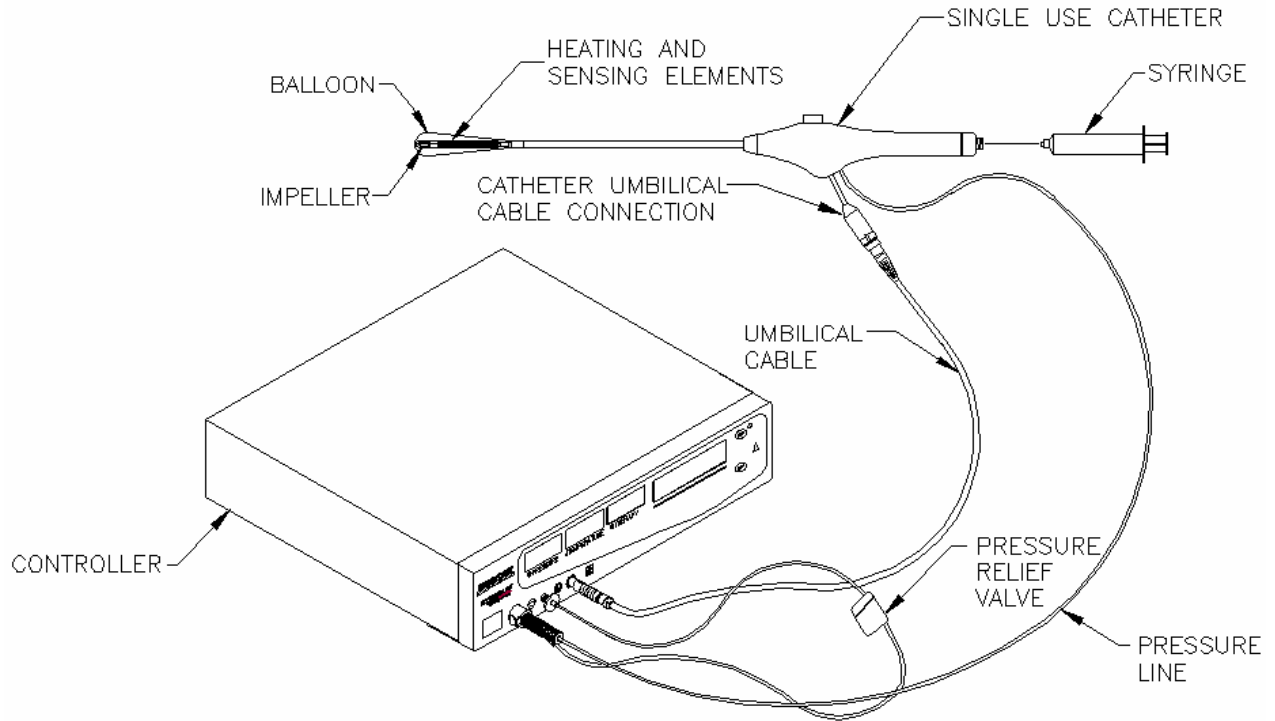


Figure 1-1

Device Description

The THERMACHOICE™II UBT System is a software-controlled device designed to ablate uterine tissue by thermal energy. The system is comprised of a single-use balloon catheter, a reusable controller, umbilical cable, and power cord. The THERMACHOICE™II UBT catheter is designed for use only with the THERMACHOICE™II UBT controller.

The balloon catheter is 1) connected to the controller, 2) inserted through the cervix into the uterus, 3) filled with sterile, injectable fluid (plain 5% dextrose in water – D₅W) carefully stabilizing the pressure to 160-180 mmHg pressure, and 4) activated to thermally ablate endometrial tissue by maintaining a temperature of approximately 87°C (188°F) for 8 minutes.

The THERMACHOICE™II UBT controller is designed to work with 3 different versions of the balloon catheter. They are:

- a) ***Balloon catheter version 2.0:*** This balloon catheter has a fluid circulation mechanism inside the balloon.
- b) ***Balloon catheter version 1.4:*** This version does not have a fluid circulation mechanism inside the balloon.

- c) ***Balloon catheter version 1.2:*** This version does not have a fluid circulation mechanism inside the balloon.

Indications

The THERMACHOICE™II UBT System is a thermal ablation device intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

Functional Description of Circuits

Purpose

The purpose is to describe the THERMACHOICE™II Uterine Balloon Therapy (UBT) system and to give an overview of the functional components that make up the electronic unit, referred to as the controller. The document as written should aid the technician in troubleshooting the product for service and manufacturing assembly.

Scope

This document is limited to the controller.

Product Overview

The THERMACHOICE™II Uterine Balloon Therapy (UBT) system is an instrument designed to ablate endometrial tissue in the uterus, where excessive uterine bleeding is diagnosed. A balloon on a semi-rigid plastic catheter containing a resistive heating element is inserted into the uterus and manually filled with sterile D5W to a pre-specified pressure range. The fluid is then heated to 87° C and maintained at that temperature for the duration of the 8-minute therapy cycle.

The UBT system normalizes or alleviates the excessive uterine bleeding by ablating the endometrial lining within the uterus utilizing a thermal ablation technique. The thermal ablation process uses heated fluid to cause endometrial tissue necrosis during the treatment cycle. The fluid in the balloon is maintained under pressure to increase the balloon surface area contact with the endometrium and to reduce the blood flow to the endometrium by tissue compression and hence increase the thermal ablation penetration.

The UBT system consists of a controller, a disposable catheter, an umbilical cable, and a power cord. The catheter houses the heating element and two thermocouples in the balloon and a stirring device in newer models. The pressure transducer is internal to the controller with the pressure port located on the front panel of the controller. The fluid transport mechanism is manual and external to the controller. The UBT controller is a microprocessor based system with a LCD for displaying messages, LED displays for displaying time, temperature, and pressure, and alarms.

To use the system, the catheter is first connected to the controller via the umbilical cable pressure line to the pressure port and motor drive unit (MDU) port, on the front panel of the controller. The power is then turned on. After purging the balloon and its placement into the uterus, the balloon is filled with sterile D5W to a pre-specified pressure. Pressing the start button will initiate the preheat cycle. Once the desired temperature is reached the controller will start the therapy cycle. Heating is automatically stopped after the therapy cycle is completed or if a fault is detected. The LCD display along with LED displays and alarms, inform the user of the status of the procedure and the pertinent parameters, pressure, temperature, stirring status, and time throughout the procedure. The background diagnostic routines continuously monitor the integrity of the controller operations.

Functional Sections

- Power Supplies and Isolation
- Temperature Measurement
- Pressure Measurement
- Heater Drive and Protection

Motor Drive Unit (MDU)
Central Processing Unit (CPU)
User Interface, Front Panel Display

For more information regarding the procedure set up, operation of the device, messages, error conditions, unit calibration, etc. refer to Appendix A of the User Manual.

Transformer, Power Supplies and Isolation

The system operates on 100 to 240 VAC and 60 Hz power lines. The line operated power supply is auto input ranging and needs no adjustment. The power entry module consists of a conducted line noise filter and a sub-module with two fuses. The two fuses break neutral and line. The front panel power switch breaks the line and neutral side of the primaries between the rear power module and the power supply.

The line operated power supply is medical grade. The power supply also provides 4000 Volts of reinforced (Double-Plus) isolation between the primary and at the secondary side. The power supply outputs +24V, +5V, +12V, -12V. The 24 Volts is used for the MDU and heater. The 5 Volts is used for logic power. The ± 12 Volts are used for analog circuitry. (See Functional Block Diagram in Appendix A.)

The thermocouple amplifiers and their power up test circuitry are powered by two isolated +5V to ± 12 -Volt power supply. The isolation is to allow proper thermocouple operation in proximity to the heater and not to isolate the patient. The block diagram in Appendix A illustrates the system power supply configuration as well as interactions of different subsystems of the unit. As indicated, the communication between different subsystems is accomplished serially through the use of analog isolation amplifiers.

The power supply is of a switching type with the ± 12 Volts being linearly regulated.

Temperature Measurement

The temperature measurement inside the catheter balloon is accomplished by using two "K" type thermocouples. One of the thermocouples, referred to as TC1, is used as the feedback in controlling the heater. The value of this thermocouple is displayed by one of the LED displays on the controller front panel. The second thermocouple reading is used only as a check against TC1 reading. This value is not displayed.

The low level thermocouple signals are transmitted to the controller via the umbilical cable. The raw signals are amplified by use of thermocouple amplifiers.

These are two of the nine inputs to the multiplexing analog-digital converter (ADC). The ADC is a high precision serial ADC that operates from an independent voltage source and a 5.000 VDC precision voltage reference.

The positive and negative terminals of each of the two thermocouples are connected to the inputs of the amplifiers through two single pole double throw relays. These relays are used at power up to switch the inputs of the amplifiers to a 3.25 mV reference to check for any accuracy in the measurement channels.

The cold junction compensation is done by the thermocouple ICs (AD595 thermocouple amps). These ICs are thermally bonded to the cold junctions. Each IC measures the offset caused by the cold junctions and adds it to the output voltage of the thermocouples, which produces the corrected measured temperature.

Pressure Measurement

The balloon pressure measurement is accomplished by the use of two pressure transducers inside of the controller. The catheter balloon is connected to the pressure port located on the front panel of the controller via a pressure tube. The port is in turn connected to the transducers inside the controller unit. To stop the fluid from flowing back inside the controller when the catheter is pressurized, the catheter pressure line is equipped with a filter that is permeable to air only.

The transducer is of a differential type, which measures the balloon pressure relative to the atmospheric pressure. The pressure measurement is similar to that of the temperature measurement. The raw transducer signals are amplified and fed to the multiplexing ADC.

These transducers need to be biased approximately halfway in their output range so they can output negative pressures. There is no adjustment for this zero point so each new unit must be calibrated by entering calibration mode. The zero point of each transducer is measured (with no pressure port attachment) and written into the nonvolatile memory of the 68 HCII microprocessor.

Heater Drive and Protection Circuitry

The software that controls the heater uses a proportional – integral algorithm that varies the power from 0 to 60 watts to heat and maintain the temperature of the fluid. During heat up, the power is limited if the temperature ramps faster than 2 degrees per second leading to a minimum heat up time of about 30 seconds. The software heater control algorithm regulates to a constant set point of 87° C after the initial heat up.

The current in the heater is constantly monitored while the heater voltage is greater than 2.8 volts. If the current is less than 0.14 amps or greater than 2.5 amps, the controller will shut down with and generate an Error 65. If the heater voltage varies more than +/- 10% from the desired control voltage, the same error is generated.

The heater is powered from a 28 VDC SEPIC (Single Ended Primary Inductance Converter) topology regulator. The heater load is nominally at 13.2 ohms. Therefore, the nominal current of the heater is about two amps. The SEPIC regulator has three control inputs. 1) 0 - 5 volts in to control; 0 - 28 volts out. 2) HEATER_1_ON* and HEATER_2_ON*. HEATER_1_ON* enables the switching IC in the power supply. HEATER_2_ON* enables a series pass transistor to the heater and simultaneously disables a short circuit short transistor. These transistors cannot both be on at the same time. If this were to happen, the shunt transistor would draw all of the SEPIC output through a 4 amp fuse, blowing it. This is to cover the short circuit failure of the series pass transistor.

During preheat, the temperature is checked to make sure it is rising at least 2 degrees every 10 seconds. This test is intended to catch the unlikely dual fault condition of two shorted thermocouples. If the measured temperature persistently fails to meet the criteria for 30 seconds, an error is declared.

The temperature must also reach the 87 ° target within four minutes to prevent a hazard from shutting the system down.

Microprocessor Circuitry

The microprocessor used in the system is a Motorola 68HC11. The processor runs at 8 MHz. The processor controls the digital displays, LCD, Alarm LED, Beeper, Start LED, therapy sequence of events, timing, heater on/off control, and RS-232 port.

Support components are the 2KB Static Memory (RAM), 56KB Electronically Programmable Read Only Memory (EPROM), and address decoding. These devices are all contained in U15 on the microboard. This one-time programmable part is a WSI PSD312-P. A special test mode or calibration mode places the unit in constant therapy cycle. The constant therapy cycle is used for burn-in testing.

The Static RAM stores intermediate values being temporarily stored by the microprocessor. This information is lost if power is turned off.

The EPROM stores the operational software for the processor.

The RS232 serial port is used only in manufacturing and for investigational purposes. It is not intended to be used by the end user. It can be used to display both thermocouples and both pressure transducer readings.

Front Panel Display, User Interface

The power switch is located on the front panel. It is an illuminated switch that breaks both line and neutral of the AC line on the primary side of the transformer.

The thermocouple temperature of the catheter, the pressure of the balloon, and the time of the procedure are displayed by three LED seven segment type displays. A sixteen by two character backlit LCD on the front panel is used as a message center, informing the user of the status of the unit and the procedure. The front panel also includes two membrane type switches. The START and the STOP switch. The START switch is used to start the PREHEAT cycle of the procedure. This switch is enabled once the balloon pressure titration has been completed. The activation of the STOP switch turns the heater off and terminates the procedure. A green start light indicator on the front panel further informs the user that the procedure can start. This light blinks when the START button is enabled. There is also a yellow hazard indicator on the front panel. This indicator lights up when a hazard condition is encountered and the system is stopped.

Two audio generators simultaneously sound all alarms. The frequency components of the Alerts and Alarms are EN475 compliant. Upon powering on the unit, the audio generators make a distinctive ding dong sound. If either the "ding" or "dong" does not sound, one of the audio generators on the AUX board is defective.

Specifications

POWER SOURCE (Controller)

Power Requirements	100 to 240VAC; 50/60 Hz; 110 watts; 3-wire grounded system
Regulation Voltage	90 to 264VAC, 47-63 Hz, single phase
Mains Fuses	250VAC, 5x20 mm 1.6A standard
Heater Fuse	250VAC, 4.0A slo-blo

MECHANICAL CHARACTERISTICS

Dimensions	Height 10.2 cm (4 in.), width 41.2 cm (16.25 in.), depth 37.0 cm (14.56 in.)
Weight	6.9 kg (15.3 lbs.) (controller only)
Case	Aluminum and impact-resistant plastic
Umbilical Cable	Length 152 cm (60 in.)

ENVIRONMENTAL CONDITIONS

Transport and Storage

Ambient temperature	-20 to +50°C
Relative humidity	20% to 85% non-condensing

Operation

Ambient temperature	10 to 40°C
Relative humidity	20% to 85% non-condensing

Electromagnetic Compatibility

ESD	Direct & Indirect: Conforms to IEC 601-1-2
EMI	Conforms to IEC 601-1-2

Leakage Currents

Patient Leakage Current	Conforms to IEC 601-1
Earth Leakage Current	Conforms to IEC 601-1

Electromagnetic Interference

In general, sensitive electronic equipment should always be positioned as far away as possible from sources of high frequency voltages and currents, such as electrosurgical generators. Moreover, cables connected to high frequency sources should be kept as short as possible and must never be routed near or parallel to cables of sensitive equipment.

Section Two

Diagnostic and Troubleshooting Guide

Error Codes

The instrument will perform a power-up self test every time the unit is started. If an error is detected, it will appear on the display if possible.

Note:

The Error Code Format is: xxyy, where xx=error code and yy=system state. Reference the first two numbers on the display for use with the table below.

<u>Problem or Error No.</u>	<u>Probable Source of Problem</u>	<u>Notes</u>
Blank Display no Audio	Power Supply, Micro Board, Display, ISO Board, or AUX Board	
Blank Display w/ Audio 00, 01, 02, 03, 12	Micro or Display Micro	If unit consistently displays these unused error codes
MDU Warning 17 26, 29, 30 28, 31, 33, 35 50, 58, 68	MDU PS or Micro AUX or Micro ISO or Micro Disposable or Umb or ISO or Placement	
59, 60, 61, 64 66	AUX or PS	Test Procedure Update Required, Check output of TP19, and TP31
62, 63 65	Micro or Pressure Fittings & Lines AUX or ISO or Micro	

Diagnostic and Troubleshooting Decision Trees

The following pages contain diagnostic and troubleshooting flowcharts.

Warning:

The following diagnostic and troubleshooting flowcharts, the repair procedures in Section Four, and the controllers's start-up diagnostic test will not detect faults in the heater circuit or the motor drive unit. If you suspect a problem with either of these field replaceable units, send the device to the authorized Gynecare service center.

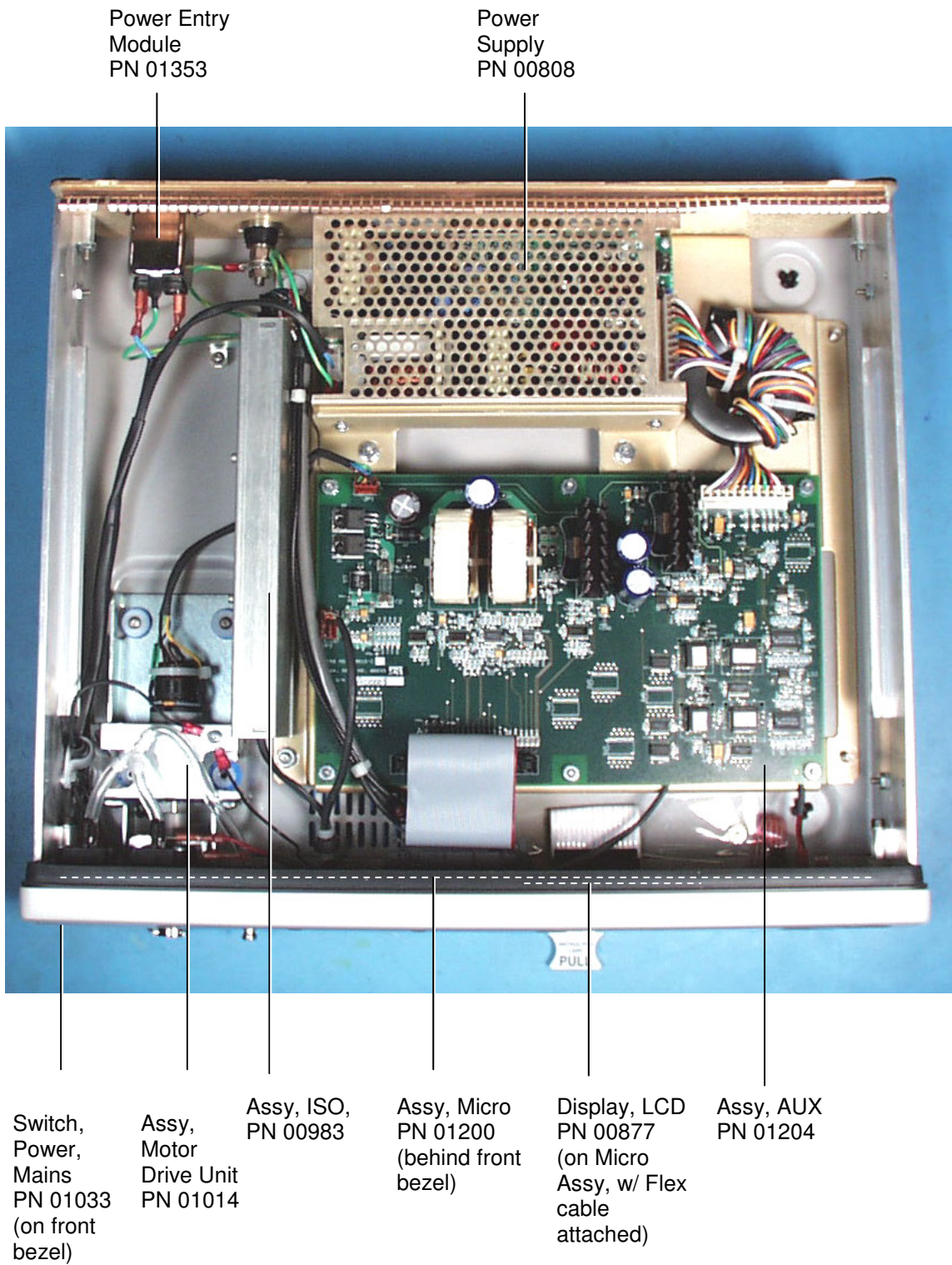
Notes:

1. Decision trees cover single faults.

2. First troubleshooting step should be to perform a visual inspection of the connectors making sure they are seated properly.
3. Check FRUs by swapping out the suspect FRU with a known good FRU.
4. Replace the Micro Assembly to correct problems with the Pressure display, Temperature display, Time display, Start Button Light, or the Hazard Light.
5. Replace the Front Panel Assembly to fix problems with the Start and Stop buttons.
6. Replacement of the Motor Drive Unit (MDU) may be required if the instrument consistently displays the MOTOR FAULT WARNING using known good catheters.

Section Three

Field Replaceable Units



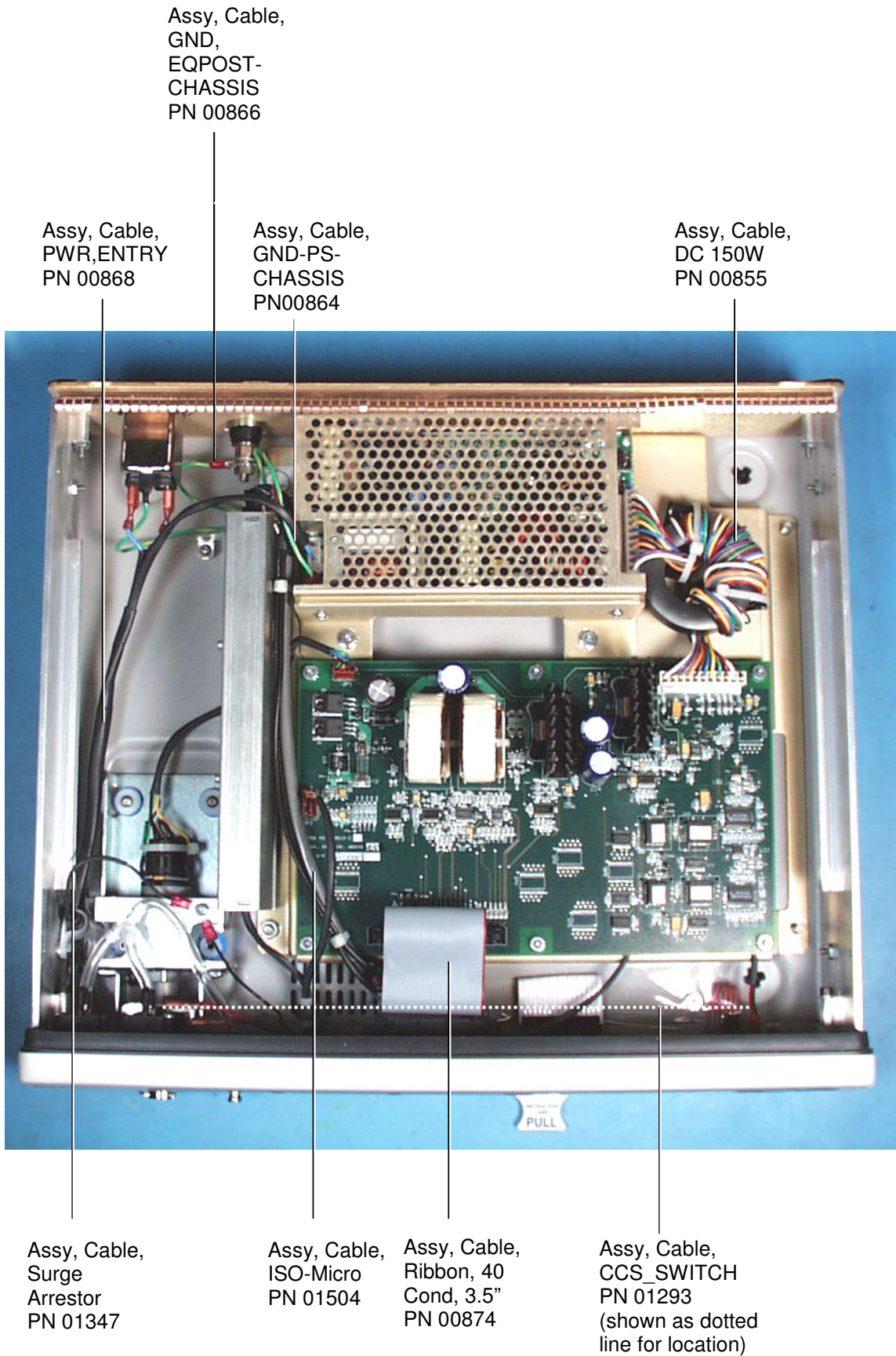
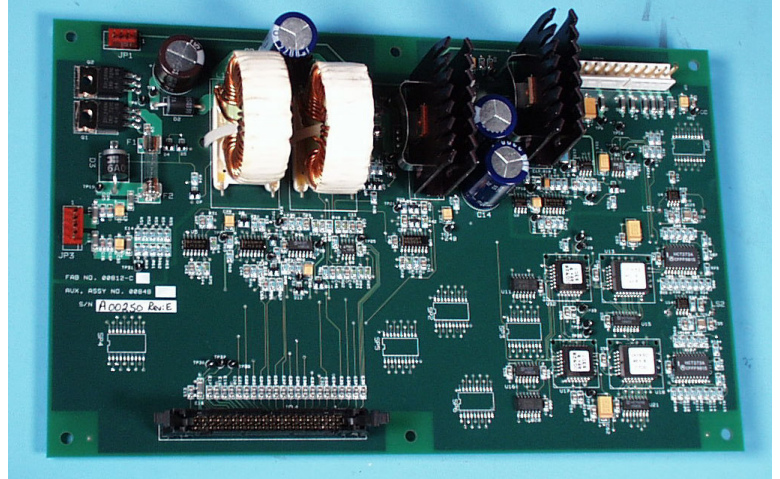


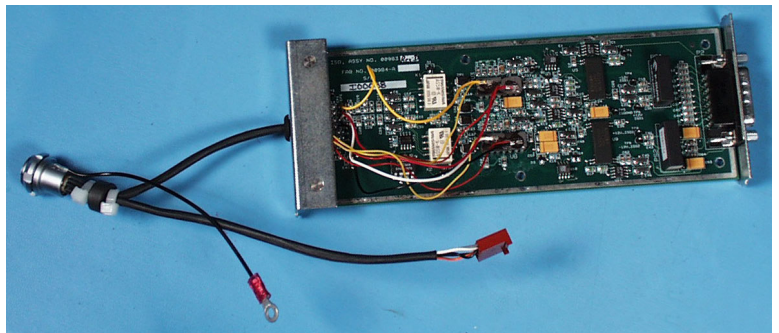
Table of Field Replaceable Units

<u>Common Name</u>	<u>Bill of Materials Designation</u>	<u>Assy No.</u>
AUX Board	ASSY,PCBA,AUXILLARY	01204
ISO Board	ASSY,PCB,ISO	00983
Micro Board	ASSY,PCBA,MICROPROCESSOR	01200
Motor Drive Unit (MDU)	ASSY,MOTOR DRIVE UNIT	01014
Power Supply	PSUPPLY,UNIV INPUT,+5V,-24V-/-12V	00808
Power Entry Module (PEM)	PEM,FILTER,W/FUSEHOLDER	01353
Power Switch, Mains	SWITCH,SPDT,AMP,.187"TERM,MDU	01033
LCD Display	DISPLAY, LCD,16X2,BACKLIT	00877
Heater Fuse	Fuse, 5X20MM, SLOWBLOW, 4.0A,250	01620
Power Entry Module Fuse	Fuse, 5X20MM, FASTBLOW, 1.6A,250	00861
Eqpost Ground Cable	Assy, Cable, GND, EQPOST-CHASSIS	00866
Power Entry Cable	Assy, Cable, PWR, ENTRY	00868
Ribbon Cable	Assy, Cable, RIBBON, 40 COND, 3.5"	00874
CCS Switch Cable	Assy, Cable, CCS_SWITCH	01293
ISO-Micro Cable	Assy, Cable, ISO-MICRO	01504
Power Supply Cable	Assy, Cable, DC, 150W	00855
Power Supply Ground Cable	Assy, Cable, GND-PS-CHASSIS	00864
Surge Arrestor Cable	Surge Arrestor Cable	01347

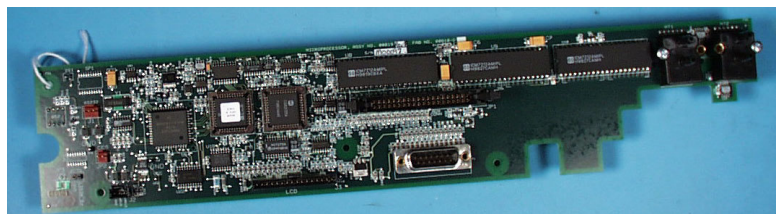
AUX Board
ASSY,PCBA,AUXILLARY
PN 01204



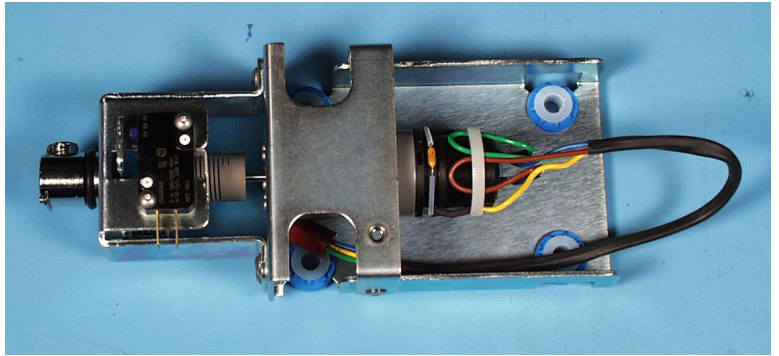
ISO Board
ASSY,PCBA,ISO
PN 00983



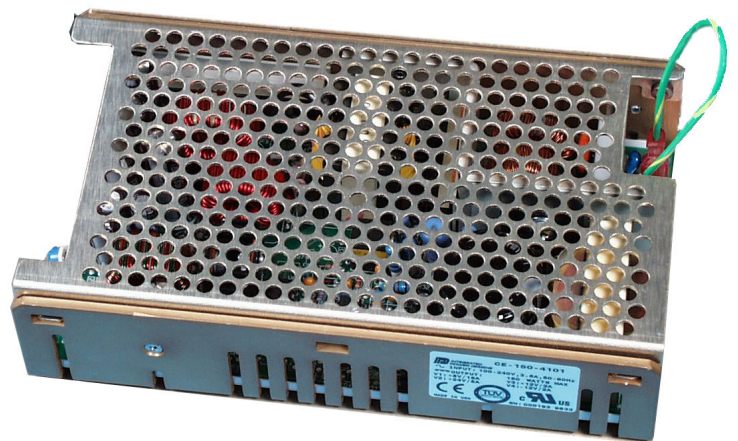
Micro Board
ASSY,PCBA,
MICROPROCESSOR
PN 01200



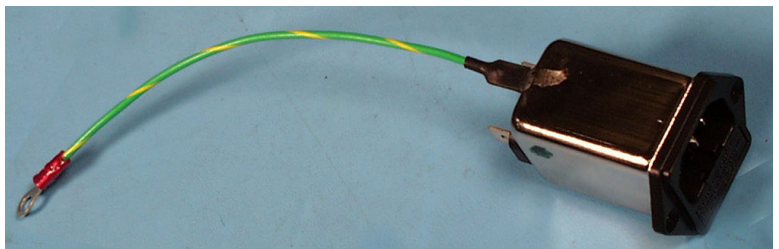
Motor Drive Unit
ASSY,MOTOR DRIVE UNIT
PN 01014



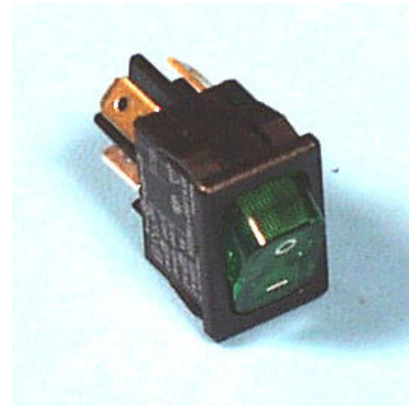
Power Supply
PSUPPLY,UNIV INPUT,+5V,-24,V-
/-12V
PN 00808
(ground cable not included)



Power Entry Module
PEM,FILTER,
W/FUSEHOLDER,
3A,.250"TERM
PN 01353



Power Switch
SWITCH,SPDT,3AMP,.187"TERM,MDU
PN 01033



LCD Display
DISPLAY,LCD,16X2,BACKLIT
PN 00877



Note: Assy, Cable, FLEX, 1X16,4.5", LCD is attached
PN 00881

Heater Fuse

**FUSE,5x20MM,SLOWBLOW,4,0A,250
PN 01620**

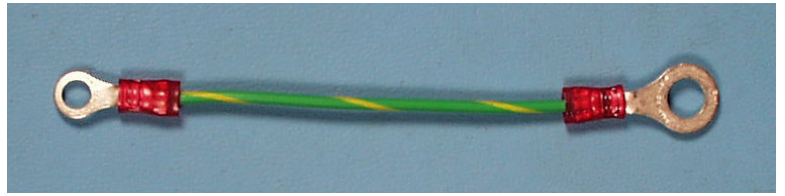


Power Entry Module Fuse

**FUSE,5x20MM,FASTBLOW,1.6A,250
PN 00861**



Eqpost Ground Cable
ASSY,CABLE,GND,
EQPOST-CHASSIS
PN 00866



Power Entry Cable
ASSY,CABLE,POWER,ENTRY
PN 00868



Ribbon Cable

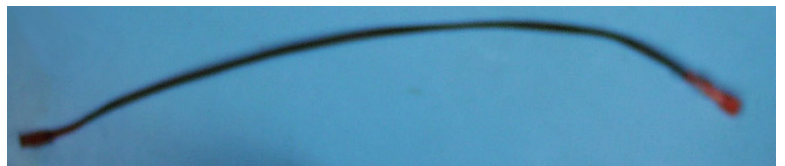
**ASSY,CABLE,RIBBON,40COND,
3.5"**

PN 00874



CCS Switch Cable

**ASSY,CABLE,CCS_SWITCH
PN 01293**



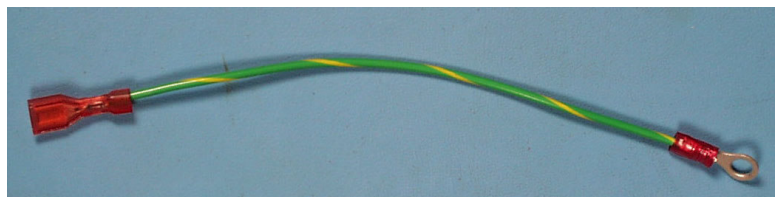
ISO-Micro Cable
ASSY,CABLE,ISO-MICRO
PN 01504



Power Supply Cable
ASSY,CABLE,DC,150W
PN 00855



Power Supply Ground Cable
ASSY,CABLE,GND-PS-CHASSIS
PN 00864



Surge Arrestor
ASSY,CABLE,SURGE
ARRESTOR
PN 01347



Section Four

Repair Procedures

Assembly, AUX Board 01204

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 5/16" nut driver

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Remove the connections from the AUX Board JP1, JP2, JP3 and JP4.
3. Using the 5/16" nut driver, remove the 6 keps nuts retaining the AUX Board.
4. Remove the AUX Board.

Replacement:

Notes:

- 1) Prior to the replacement of the AUX Board, confirm that 6 mounting stud spacers are present.
- 2) Upon installation, position the AUX Board so that the speakers are above the holes within the lower case.

1. Using the 5/16" nut driver, install the 6 keps nuts. Torque 89 – 91 in./oz.
2. Reconnect JP1-JP4 to the AUX Board. Note the routing of the ISO-Micro Cable (Page 3-2)
3. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Assembly, ISO Board 00983

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 3/32" Allen wrench, needle nose pliers, #1 Phillips screwdriver, 9/64" Allen wrench

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Using a 3/32" Allen wrench, remove the two 4-40 socket head cap screws from the ISO box.
3. Remove the ISO box cover.
4. Remove the connection from AUX Board at JP3.
5. Remove ISO Board from box base.
6. Using the #1 Phillips screwdriver, remove 2 Phillips screwdriver head screws from the P2 Cable connector.
7. Place the controller unit on its right side.

Note:

The following two steps involve spring loaded parts. Use care to cover the circulation connector during disassembly to prevent loss of parts.

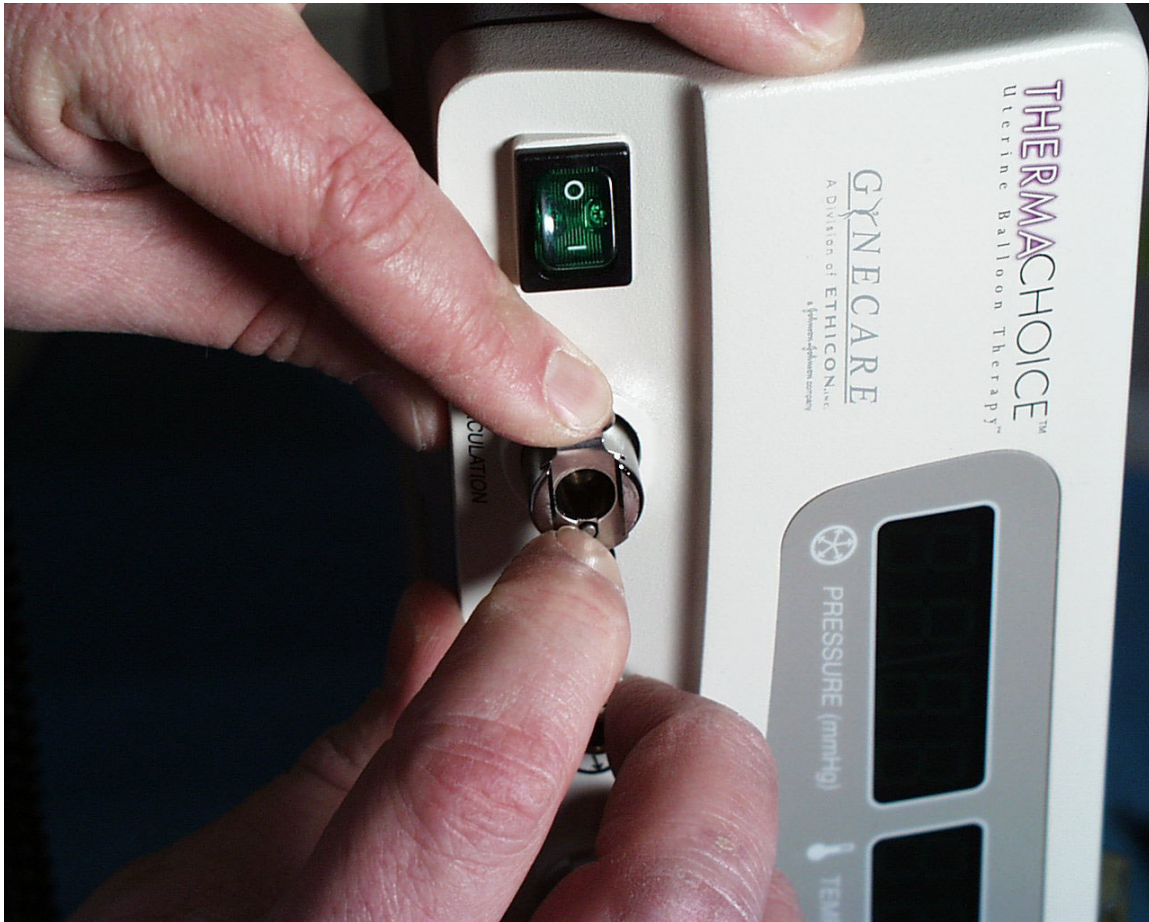


Illustration showing depressing of latch retention pin for latch disassembly. Use caution: both latch and retention pin are spring loaded.

8. Slide the circulation connector slide lock in so that you can depress the retention pin into the circulation connector and covering the connector with your hand, slowly release the slide lock until the retention pin and spring are released.
9. Remove the springs and retention pin from the circulation connector.
10. Place the unit on its base.
11. Use a 9/64" Allen wrench to remove the 2 screws holding the front panel to the sides.
12. Disconnect the ribbon cable from the JP1 connector on the Micro board.
13. Using the #1 Phillips screwdriver, remove the fastener securing the Surge Arrestor Ground and Patient Cable ground from the MDU mounting bracket.
15. Disconnect the Power Entry Cable from the Power Entry Module and the Power Supply.
16. Tilt the front panel forward.

17. Use a #1 Phillips screwdriver to remove the 5 screws, washers, and lockwashers that hold the Micro PCBA to the bezel. The Micro PCBA does not need to be separated from the bezel; it only needs to be free to move to allow the removal and installation of the umbilical cable.
18. Using the needle nose pliers, remove the Umbilical Cable retention nut from the front panel.
19. Remove the Umbilical Cable connector from the front panel.
20. Remove the ISO Board assembly from the controller unit.

Replacement:

1. Install the Umbilical Cable connector through the front panel – red dot up.
2. Install the Umbilical Cable connector retention ring using the needle nose pliers.
3. Use the #1 Phillips screwdriver to attach the 5 screws, washers, and lockwashers that hold the Micro PCBA to the bezel. Torque the fasteners at 59-61 in./oz.
4. Reattach the front panel to the sides using the 9/64" Allen wrench. Torque the fasteners to 89-91 in./oz.
5. Install the springs and retention pin into the circulation connector.
6. Depressing the retention pin into the circulation connector, install slide lock with the tab towards the bezel so that the retention pin engages the slide lock and the two springs are retained.
7. Using the #1 Phillips screwdriver, secure the ISO Micro Cable to the P2 connector.
8. Position and install the ISO Board into the ISO box base.
9. Install the ISO box cover.
10. Install the Umbilical Cord Cable connector to the AUX Board JP3.
11. Using the #1 Phillips screwdriver, install the grounding wires from the Patient Cable and surge suppressor to the MDU mounting bracket. Torque the fasteners to 79 – 81 in./oz.
12. Reattach the ribbon cable to JP1 on the Micro board.
13. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Power Supply 00808

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), #1 Phillips screwdriver, 5/64" Allen wrench, 3/8" nut driver, 5/16" nut driver, VOM Meter, 3/32" Allen wrench.

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Using a 3/32" Allen wrench, remove the two 4-40 socket head cap screws from the ISO box.
3. Remove the ISO box cover.
4. Remove the connection from the AUX Board JP1, JP3 and JP4.
5. Remove the ISO Board from the box base.
6. Use the 5/64" Allen wrench to remove the 5 fasteners holding the ISO box to the case and remove the ISO box base.
7. Using the 3/8" nut driver, remove the keps nuts from the grounding stud.
8. Remove the Power Supply ring lug from the grounding stud.
9. Remove the lock washer from the grounding stud.
10. Remove the equipotential grounding wire ring lug from the grounding stud.
11. Remove another lock washer from the grounding stud.
12. Using the 3/8" nut driver, remove the keps nut from the grounding stud.
13. Remove the Power Entry Module grounding wire's ring lug from the grounding stud.
14. Disconnect the Power Supply input wires P1-L, P1-N, ground, and P2.
15. Using the 3/8" nut driver, remove the 3 remaining keps nuts from the sub-chassis.
16. Remove the sub-chassis from the lower case.
17. Using the 5/16" nut driver, remove the keps nut and washers from the power supply's support bracket.
18. Flip over the sub-chassis.
19. Using the #1 Phillips screwdriver, remove the four fasteners that retain the Power Supply to the sub-chassis.
20. Remove the Power Supply from the sub-chassis.
21. Using the #1 Phillips screwdriver, remove the Power Supply support bracket from the Power Supply.

Replacement:

1. Using the #1 Phillips screwdriver, install the Power Supply support bracket to the Power Supply. Torque at 89 – 91 in./oz.
2. Install the Power Supply to the sub-chassis using 4 fasteners and lock washers. Torque the fasteners at 89 – 91 in./oz.

3. Install the Power Supply support bracket to the sub-chassis with 2 keps nuts and 2 washers. Torque at 89 –91 in./oz.
4. Install the sub-chassis onto the thread studs of the lower housing.
5. Secure the sub-chassis to the lower housing using 3 keps nuts positioned in the upper right and lower left and right.
6. On the fourth threaded stud, install the grounding lug sequence
7. Install the Power Entry Module Ground wire onto the lower case stud.
8. Install the keps nut. Torque at 17 - 19 in./lbs.
9. Install 1 lock washer onto same lower case stud.
10. Install the equipotential Ground wire onto lower case stud.
11. Install 1 lock washer onto lower case stud.
12. Install the Power Supply Ground wire onto the lower case stud.
13. Position the Ground wire lugs in a radial fashion away from the ISO Board box area.
14. Install the keps nut. Torque at 17 - 19 in./lbs.
15. Connect Power Supply P1-L, P1-N, ground, and P2.
16. Reconnect JP1, JP3 and JP4 on the Aux board.
17. Install the ISO box base into the lower case using the 5 fasteners and the 5/64" Allen wrench. Torque the fasteners to 39 – 41 in./oz.
18. Position and install the ISO Board into the ISO box base.
19. Perform the Power Supply Adjustment
 - a) Plug the Controller into a standard 120VAC/60Hz power outlet
 - b) Set the digital multimeter (DMM) to read DC Voltage on Auto-Range (able to read 0.01 volts).
 - c) Connect the positive input of the DMM to TP9 on the Micro PCBA
 - d) Connect the negative input of the DMM to TP7 on the Micro PCBA.
 - e) Locate the Power Supply's output voltage adjustment potentiometer near the supply's output connector.

CAUTION: Do not increase the voltage past 5.10 VDC or the Controller may be damaged.
 - f) If the output voltage reading on the DMM is less than 5.07 VDC, use a small flat blade screwdriver to slowly turn the potentiometer to increase the voltage to a value of 5.07 +/- 0.01 VDC.
 - g) If the output voltage reading on the DMM is greater than 5.08 VDC, use a small flat blade screwdriver to slowly turn the potentiometer to decrease the voltage to a value of 5.07 +/- 0.01 VDC.
 - h) Turn the Controller OFF.
 - i) Apply a small amount of Torque-Seal onto the Power Supply's output potentiometer.
20. Install the ISO box cover and the 2 screws holding the cover to the box base.

21. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Power Entry Module (PEM) 01353

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), #1 Phillips screwdriver, 3/32" Allen Wrench, 5/64" Allen wrench, 3/8" nut driver, Loctite Adhesive #425

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Disconnect the two fast-on connectors from the Power Entry Module.
3. Disconnect the Power Entry Cable from the Power Supply.
4. Using a 3/32" Allen wrench, remove the two 4-40 socket head cap screws from the ISO box.
5. Remove the ISO box cover.
6. Remove the ISO Board by lifting vertically, and place it parallel to the front bezel.
7. Remove the 5 fasteners holding the ISO box base to the standoffs using the 5/64" Allen wrench and remove the ISO box base.
8. Using the 3/8" nut driver, remove the keps nuts from the grounding stud.
9. Remove the Power Supply ring lug from the grounding stud.
10. Remove the lock washer from the grounding stud.
11. Remove the equipotential grounding wire ring lug from the grounding stud.
12. Remove another lock washer from the grounding stud.
13. Using the 3/8" nut driver, remove the keps nut from the grounding stud.
14. Remove the Power Entry Module grounding wire's ring lug from the grounding stud.
15. Using the #1 Phillips screwdriver, remove the two fasteners retaining the Power Entry Module to the rear panel.
16. Remove the Power Entry Module from the rear panel.

Replacement:

1. Remove the fuse drawer from the Power Entry Module using a flat blade screwdriver.
2. Remove and verify that fuses are 250V, 1.6 amp fuses. Replace if necessary.
3. Install the fuse drawer into Power Entry Module.
4. With the fuse drawer down, position and insert Power Entry Module into rear panel.
5. Using the #1 Phillips screwdriver and Loctite adhesive #425, install the screws through the rear panel securing the PEM. Torque the fasteners at 49-51 in./oz.
6. Install the Power Entry Module Ground wire onto the lower case stud.
7. Install the keps nut. Torque at 17 - 19 in./lbs.
8. Install 1 lock washer onto same lower case stud.
9. Install the equipotential Ground wire onto lower case stud.
10. Install 1 lock washer onto lower case stud.
11. Install the Power Supply Ground wire onto the lower case stud.
12. Position the Ground wire lugs in a radial fashion away from the ISO Board box area.
13. Install the keps nut. Torque at 17 - 19 in./lbs.
14. Install the fast-on connector to the Power Entry Module (brown wire to the Power Entry Module's "L" terminal – lower right. Blue wire to the Power Entry Module "N" terminal – lower left).
15. Install the Power Entry Cable to the Power Supply.
16. Install the ISO box base into the lower case using the 5 fasteners. Torque the fasteners to 39 – 41 in./oz.
17. Position and install the ISO Board into the ISO box base.
18. Install the ISO box cover and the 2 screws that hold the cover to the box base.
19. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Assembly, Motor Drive Unit (MDU) 01014

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 5/64" Allen wrench, #1 Phillips screwdriver, Loctite adhesive #425, 3/32" Allen wrench

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Disconnect the two fast-on connectors from the Power Entry Module.
3. Disconnect the Power Entry Cable from the Power Supply.
4. Using a 3/32" Allen wrench, remove the two 4-40 socket head cap screws from the ISO box.
5. Remove the ISO box cover.
6. Remove the ISO Board by lifting vertically, and place it parallel to the front bezel.
7. Using the 5/64" Allen wrench, remove 5 fasteners that retain the ISO box base to the chassis.
8. Remove the ISO box base from the chassis.
9. Disconnect the MDU motor tachometer Cable from the AUX Board – JP1 position.
10. Disconnect the two fast-on connections from the CCS Switch.
11. Using the #1 Phillips screwdriver, remove the fastener securing the Surge Arrestor Ground and Patient Cable Ground from the MDU mounting bracket.
12. Put controller unit on its right side.
13. Follow the procedure described in steps 8 and 9 in the ISO Board removal section for the removal of the springs and retention pin on the circulation connector.
14. Set the controller unit on its base.
15. Using a 5/64" Allen wrench, remove the four fasteners and 8 washers securing the MDU to the lower case.
16. Raise the MDU unit from the lower case approximately ½ in. and slide back towards the rear panel, sufficiently for the circulation connection to clear the front bezel.
17. Note: reassemble circulation connector prior to depot repair.

Replacement:

1. Insert the circulation connector through the front bezel hole.
2. Align the isolation washers over the threaded PEM studs and then lower it into the case.
3. Using the 5/64" Allen wrench, install the 8 washers and 4 fasteners. Sequence: large washer first, then small washer, followed by the fastener with the Loctite adhesive #425. Torque the fasteners to 99 – 101 in./oz.
4. Install springs and retention pin into the circulation connector.
5. Depressing the retention pin into the circulation connector, install slide lock with the tab towards bezel so that the retention pin engages the slide lock and the two springs are retained.

Note:

Ensure that the isolation washers are in place.

6. Using the #1 Phillips screwdriver, install the grounding wires from the Patient Cable and surge suppressor to the MDU mounting bracket. Torque the fasteners to 79 – 81 in./oz.

Note:

Due to different lead lengths, observe polarity when connecting the CCS Switch Cable to the CCS Switch.

7. Connect one wire of the CCS Switch Cable to the center terminal of the CCS Switch.
8. Connect one wire of the CCS Switch Cable to the 90-degree terminal of the CCS Switch.
9. Connect the motor tachometer to the AUX Board JP1 connection.
10. Install the ISO box base into the lower case using the 5 fasteners and the 5/64" Allen wrench. Torque the fasteners to 39 – 41 in./oz.
11. Position and install the ISO Board into the box base.
12. Install the ISO box cover.
13. Using a 3/32" Allen wrench, secure the two 4-40 socket head cap screws to the ISO box.
14. Reattach the Power Entry Cable to the Power Supply.
15. The position of the catheter coupling on the MDU motor shaft must be set using the procedure defined in the Controller Assembly Procedure 00953 with the 01374 alignment gage that has been calibrated using procedure 01006.
16. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Heater Fuse 01620**Warning:**

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Tools needed: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), Flat blade screwdriver

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.

2. On the AUX Board, at location F1F2, remove and inspect the 250V 4.0 amp fuse.

Replacement:

Caution:

Replace only with 250V, 4.0 amp slo-blo fuses

1. Replace the fuse if necessary.
2. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Power Entry Module Fuse 00861

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Tools needed: Flat blade screwdriver

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Remove the fuse drawer from the Power Entry Module using a flat blade screwdriver.
2. Remove and inspect the 250V 1.6 amp fuses

Replacement:

Caution:

Replace only with 250V, 1.6 amp fuses.

1. Replace the fuses if necessary.
2. Install the fuse drawer into the Power Entry Module.
3. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Assembly, Micro (Micro) 01200

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 9/64" Allen wrench, 5/64" Allen wrench, #1 Phillips screwdriver, 3/32" Allen wrench, needle nose pliers

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Put controller unit on its right side.
3. Follow the procedure described in steps 8 and 9 in the ISO Board removal section for removal of the springs and retention pin of the circulation connector.
4. Set controller unit on its base.
5. Use the 3/32" Allen wrench to remove the 2 4-40 socket head cap screws that hold the ISO box cover to the box base.
6. Remove the ISO boards from the ISO box base.
7. Using the 9/64" Allen wrench, remove the 2 socket head cap screws which retain the front bezel to the side extrusion.
8. Disconnect the ribbon cable from the JP1 connector on the Micro board.
9. Using the #1 Phillips screwdriver, remove the fastener securing the Surge Arrestor Ground and Patient Cable Ground from the MDU mounting bracket.
10. Disconnect the connector at JP3 on the AUX board.
11. Disconnect the Power Entry Cable from the Power Entry Module and the Power Supply.
12. Grasp the front bezel and tilt it forward.
13. Remove the 5 fasteners with their associated lock washers and washers that hold the MICRO PCBA to the bezel
14. Using the 3/32" Allen wrench, remove the fasteners securing the connector at the Micro Board location P1 and remove the cable.
15. Disconnect the Micro Board electrical connections CCS, J2, J3.
16. Using the #1 Phillips screwdriver, remove the tygon tubing from the luer fitting.

Caution:

Removal of tubing may result in damage to tubing, pressure transducers, and fittings. If it is necessary to remove Tygon tubing, cut tubing flush with pressure transducer nipples on micro board.

17. Grasp and remove the Micro Board from the bezel.

Replacement:

1. Install the Micro Board onto the front bezel with the 5 fasteners, washers and lock washers. Torque the fasteners at 59 – 61 in./oz.

Caution:

1. Over tightening fasteners in Step 4 will damage inserts.
2. Attach and secure with fasteners, the ISO Cable to the Micro D-Sub P.
3. Install the tygon tubing to the luer fitting.
4. Position the Front Bezel on the chassis. Note position of mylar insulation is inside of chassis.
5. Using the 9/64" Allen wrench, fasten the 2 socket head cap screws which retain the front bezel to the side extrusion. Torque screws to 89-9in./oz.
6. Install the springs and retention pin into the circulation connector.
7. Depressing the retention pin into the circulation connector, install slide lock with the tab towards the bezel so that the retention pin engages the slide lock and the springs are retained.
8. Attach the Ribbon Cable to the Micro Board JP1.
9. Attach the Display flex Cable to the Micro Board LCD J3.
10. Attach the controller overlay Flex Cable to the Micro Board J2.
11. Attach the CCS Switch Cable to the Micro Board CCS JP2.
12. Reconnect the Power Entry Cable to the Power Supply.
13. Reconnect the fast-on connectors to the Power Entry Module.
14. Reinstall the ISO board into the ISO box base.
15. Reinstall the ISO cover to the ISO box base using the 2 4-40 socket head cap screws.
16. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

LCD Display 00877

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 9/64" Allen wrench, 5/64" Allen wrench, #1 Phillips screwdriver, 3/32" Allen wrench, needle nose pliers

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Put controller unit on its right side.
3. Follow steps 3 through 17 in the Micro Board removal section to gain access to the LCD Display.
4. Remove the four fasteners with their associated lock washers and washers securing the LCD Display
5. Lift out the LCD Display.

Replacement:

1. Remove the protective cover from the LCD Display.
2. Secure the LCD Display with the four fasteners, washers and lock washers. Torque the fasteners at 59 – 61 in./oz.
3. Follow steps 1 through 16 in the Micro board replacement section to complete the replacement process.

Switch, Power, Mains 01033

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 9/64" Allen wrench, 5/64" Allen wrench, #1 Phillips screwdriver, 3/32" Allen wrench, needle nose pliers

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Disconnect fast-on connectors from the CCS Switch.
3. Put controller unit on its right side.

4. Follow the procedure described in steps 8 and 9 in the ISO Board removal section for removal of the springs and retention pin of the circulation connector.
 5. Set controller unit on its base.
 6. Using the 9/64" Allen wrench, remove the 2 socket head cap screws which retain the front bezel to the side extrusion.
 7. Using the #1 Phillips screwdriver, remove the fastener securing the Surge Arrestor Ground and Patient Cable Ground from the MDU mounting bracket.
 8. Remove the connectors from AUX Board JP3 and JP4.
 9. Disconnect the Power Entry Cable from the Power Supply.
 10. Disconnect the fast-on connectors from the Power Entry Module.
 11. Use the 3/32" Allen wrench to remove the two 4-40 socket head cap screws that hold the ISO cover to the ISO box base. Remove the cover.
 12. Remove the ISO board from the ISO box base.
- Grasp the front bezel and tilt it forward.
15. Disconnect fast-on connectors from the Power Switch.
 16. Depress the locking tabs and remove the switch from the front panel.

Replacement

1. Insert Power Switch into front panel with OFF position ("0") to the left.

Note:

Observe the labeling on the connectors of the Power Entry Cable to attach the cable to the Power Switch.

2. Connect the Power Entry Cable connector labeled P3 to the Power Switch terminal.
3. Connect the Power Entry Cable connector labeled P6 to the Power Switch terminal 6.
4. Connect the Power Entry Cable connector labeled P2 to the Power Switch terminal 2.
5. Connect the Power Entry Cable connector labeled P5 to the Power Switch terminal 5.
6. Position the Front Bezel on the chassis. Note position of mylar insulation is inside of chassis.
7. Using the 9/64" Allen wrench, fasten the 2 socket head cap screws which retain the front bezel to the side extrusion. Torque screws to 89-91 in./oz.
8. Install the springs and retention pin into the circulation connector.
9. Depressing the retention pin into the circulation connector, install slide lock with the tab towards the bezel so that the retention pin engages the slide lock and the springs are retained.
10. Attach the Ribbon Cable to the Micro Board JP3 and AUX board JP4.
11. Attach the faston connectors from the CCS Switch Cable to the CCS switch.
12. Attach the Power Entry Cable to the Power Supply.

13. Attach the Power Entry Cable faston connectors to the Power Entry Module (blue wire – lower left, brown wire – lower right).
14. Install the ISO board in the ISO box base.
15. Install the ISO cover onto the ISO box base including the 2 4-40 socket head cap screws.
16. Use the #1 Phillips screwdriver to reattach the surge arrestor cable to the MDU chassis.
17. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Power Entry Cable 00868

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required Tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), 9/64" Allen wrench, 5/64" Allen wrench, #1 Phillips screwdriver, 3/32" Allen wrench, needle nose pliers

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Put controller unit on its right side.
3. Follow the procedure described in steps 8 and 9 in the ISO Board removal section for removal of the springs and retention pin of the circulation connector.
4. Set controller unit on its base.
5. Use the 3/32" Allen wrench to remove the 2 4-40 socket head cap screws that hold the ISO box cover to the ISO box base.
6. Remove the ISO board from the ISO box base.
7. Disconnect the connector from the AUX board at JP3.
8. Using the 9/64" Allen wrench, remove the 2 socket head cap screws which retain the front bezel to the side extrusion.
9. Using the #1 Phillips screwdriver, remove the fastener securing the Surge Arrestor Ground and Patient Cable Ground from the MDU mounting bracket.
10. Disconnect the Power Entry Cable from the Power Supply.

11. Disconnect the fast-on connectors from the Power Entry Module.
12. Disconnect the ribbon cable from the Micro board at JP1.
13. Grasp the front bezel and tilt it forward. Disconnect fast-on connectors from the Power Switch.

Replacement

Note:

Observe the labeling on the connectors of the Power Entry Cable to attach the cable to the Power Switch.

1. Connect the Power Entry Cable connector labeled P3 to the Power Switch terminal 3.
2. Connect the Power Entry Cable connector labeled P6 to the Power Switch terminal 6.
3. Connect the Power Entry Cable connector labeled P2 to the Power Switch terminal 2.
4. Connect the Power Entry Cable connector labeled P5 to the Power Switch terminal 5.
5. Position the Front Bezel on the chassis. Note position of mylar insulation is inside of chassis.
6. Using the 9/64" Allen wrench, fasten the 2 socket head cap screws which retain the front bezel to the side extrusion.
7. Install the springs and retention pin into the circulation connector.
8. Depressing the retention pin into the circulation connector, install the slide lock with the tab towards the bezel so that the retention pin engages the slide lock and the two springs are retained.
9. Install the faston connector to the Power Entry Module (brown wire to the Power Entry Module's 'L' terminal - lower right and the blue wire to the Power Entry Module's 'N' terminal – lower left).
10. Install the Power Entry Cable to the Power Supply.
11. Attach the connector to the AUX board JP3.
12. Attach the ribbon cable to the Micro board JP1.
13. Use the #1 Phillips screwdriver to attach the surge arrestor cable to the MDU chassis.
14. Assemble the ISO board to the ISO box base.
15. Attach the ISO cover to the ISO box base including the 2 4-40 socket head cap screws.
16. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Power Supply Cable 00855

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), wire cutter

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case
2. With a wire cutter, clip the two tie wraps securing the torroid to the sub-chassis.
3. Disconnect the wire bundle from the Power Supply P2 and AUX Board location JP2.

Replacement:

1. Install the new wire bundle ensuring the 12 pin connector is installed at the Power Supply P2 location and the 11 pin connector is installed at the AUX Board JP2.
2. Install two tie wraps securing the torroid to the sub-chassis
3. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners

ISO Micro Cable 01504

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required tools: 3/36" Allen wrench, #1 Phillips screwdriver

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. At the AUX Board JP4 connection, disconnect the Ribbon Cable.
3. At the Micro Board JP1 connection, disconnect the Ribbon Cable.
4. Using a 3/32" Allen wrench, remove the two 4-40 socket head cap screws from the ISO box.
5. Remove the ISO box cover.

6. Remove ISO Board from box base.
7. Using the #1 Phillips screwdriver, remove the 2 Phillips screwdriver head screws from the P2 Cable connector.
8. Using the 3/36" Allen wrench, remove the fasteners securing the connector at the Micro Board location P1 and remove the ISO-Micro Cable.

Replacement:

1. Observe the labeling on the ISO Micro Cable noting the proper connection. Using the #1 Phillips screwdriver, secure the ISO Micro Cable to the ISO Board P2 connector.
2. Position and install the ISO Board into the ISO box base.
3. Install the ISO box cover.
4. Using a 3/32" Allen wrench, secure the two 4-40 socket head cap screws into the ISO box.

Caution:

Over tightening fasteners will damage inserts.

5. Using the 3/36" Allen wrench, attach the ISO-Micro Cable to the Micro Board location P1 with the fasteners.

Note:

Ribbon Cable should arch upward.

6. At the AUX Board JP4 connection, connect the Ribbon Cable.
7. At the Micro Board JP1 connection, connect the Ribbon Cable.
8. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

CCS Switch Cable 01293

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One)

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.

2. Disconnect the Cable from the Micro Board JP2 connection.
3. Disconnect the Cable from the center and 90-degree lugs of the MDU limit switch.

Replacement:

1. Connect the Cable to the Micro Board JP2 connection.

Note:

Due to different lead lengths, observe polarity when connecting the CCS Switch Cable to the Power Switch.

1. Connect one wire of the CCS Switch Cable to the center terminal of the Power Switch.
2. Connect one wire of the CCS Switch Cable to the 90-degree terminal of the Power Switch.
3. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Ribbon Cable, 40 Cond. 00874

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One)

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. At the AUX Board JP4 connection, disconnect the Ribbon Cable.
3. At the Micro Board JP1 connection, disconnect the Ribbon Cable.

Replacement:

Note:

Ribbon Cable should arch upward.

1. At the AUX Board JP4 connection, connect the Ribbon Cable.
2. At the Micro Board JP1 connection, connect the Ribbon Cable.
3. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Assy, Cable, Surge Arrestor 01347

Warning:

Disconnect the AC power from the device before servicing. Failure to observe this precaution could result in death or injury.

Required tools: Oval security screwdriver (TR Fastenings, Montgomery Village, MD, Phone 301-947-1001, Part Description: MonoDrive One), #1 Phillips screwdriver, 5/16" Wrench for keps nut

Caution:

The interior of the instrument is ESD sensitive. Use appropriate ESD precautionary procedures.

Removal:

1. Using the Oval security screwdriver, remove the four fasteners securing the upper half of the case and remove the upper half of the case.
2. Using the #1 Phillips screwdriver, remove the fastener securing the Surge Arrestor Ground and Patient Cable Ground from the MDU mounting bracket.
3. At the grounding stud on the side of the case, use a 5/16" wrench to remove the keps nut, nylon bracket, washer, and arrestor cable.

Replacement:

1. Install the surge arrestor ring-lug to the grounding stud.
2. Install the washer.
3. Install the nylon bracket onto the surge arrestor.
4. Position and install the surge arrestor / bracket assembly onto the grounding stud.
5. Install the keps nut and torque at 79 to 81 in.-oz.
6. Install the upper half of the case, using the Oval security screwdriver to install the four fasteners.

Section Five

Maintenance

Calibration

Every time the THERMACHOICE™II UBT System is powered up, the controller checks the calibration of the temperature circuitry. The pressure measurement in the system is accomplished by utilizing two transducers. These transducers are internally calibrated and are temperature compensated which are accurate and stable over the operating range. They are also factory calibrated at installation. These pressure readings are checked against each other at power up and throughout the procedure. These sensors are of differential type, and therefore measure the balloon pressure relative to the outside atmosphere. In addition to the internal means of calibration, it is possible to ensure the proper operation of the system against other calibrated devices. This procedure is recommended to be performed on an annual basis. The procedure also needs to be carried out if it is believed that the system is behaving unexpectedly.

Note:

There are no calibration adjustments on the controller. If the unit does not meet the calibration requirements, it needs to be sent back to the manufacturer.

Pressure Calibration

Equipment List

The following equipment list or equivalent is needed to perform the procedure:

1. Pressure meter: DigiMano model DPM 2000PS. NETECH Corporation, 60 Bethpage Drive, Hickville, NY 11801, Telephone: (800) 547-6557/ (Any calibrated, NBS traceable pressure gauge with a range of at least ± 6 psi can be used).
2. Syringe: PN 309662, Becton-Dickinson. State Surgical Supply, 3380 Vincent Rd. #C, Pleasant Hill, CA 94523, Telephone: (510) 284-1060.
3. Trumpet valve: PN S5402601, Braun Medical, Inc., 824 Twelfth Ave, PO Box 4027, Bethlehem, PA 18018-0027, Telephone: (610) 266-0500.
4. T connector: PN T20-1, Value Plastics, Inc., 3350 Eastbrook Dr., Fort Collins, CO 80525, Telephone: (970) 223-0953.
5. Tubing: 0.093 ID, 0.156 OD, Norton Performance Plastics Corp, PO Box 660, Akron OH 44309-3660, Telephone: (800) 798-1539.

6. Male luer lock adapter: PN B0850402, Braun Medical, Inc., 824 Twelfth Ave., PO Box 4027, Bethlehem, PA 18018-0027, Telephone: (610) 266-0500.

Procedure:

1. With no attachments to the luer lock, apply power to the controller. The pressure display should read 0 ± 1 mmHg.
2. Assemble the digital pressure gauge, the tubing, the T connector, the trumpet valve, the male luer lock adapter, and the syringe, and connect to the connection port (luer lock) of the controller.
3. While depressing the trumpet valve, apply vacuum to the system using the syringe until the gauge reads approximately -250 mmHg.
4. Release the trumpet valve. The controller pressure reading should be within ± 10 mmHg of the gauge reading.
5. While depressing the trumpet valve, apply pressure to the system until the reading on the digital display meter indicates a pressure of approximately 250 mmHg.
6. Release the trumpet valve. The controller pressure reading should be within ± 10 mmHg of the gauge reading.

Appendix A

Schematics

Appendix B

Electrical/Electronic Parts List

Appendix C

Operating Manual